

REMARKS

Of the 18 original claims, claims 1-2, 5-12 and 15 are amended. Claims 3, 4, 13 and 14 have been cancelled. Independent claim 51 has been added. Dependent claims 52- 57 have been added. With this response, claims 1-2, 5-12, 15-18 and 51-57 are now pending.

Amendments to claims 1-2, 5-12, and 15 have been made in order to more clearly define the present invention. Support for these amendments to the claims can be found in the originally-filed specification on page 11, lines 2-19, as well as in Figures 1A-1D.

New claims 51-57 have been added to include a further embodiment of the present invention, namely an epidural catheter dispenser system that is completely controllable by one hand of a user. Support for the addition of these claims can be found in the specification and claims as originally filed on page 11, lines 2-19, and page 13, line 19—page 14, line 6, as well as in Figures 5-8.

Applicant does not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account No. 01-2508/13421.0002.NPUS00/MCA.

I. Claim objections

Claims 2 and 12 were objected to as containing several informalities in claim language. With this communication, Applicant has amended claims 2 and 12 to address these informalities, as per the Examiner's suggestions. Specifically, claims 2 and 12 have been amended to recite "the inner cavity" rather than "an inner cavity", and the phrase "wherein the proximal end piece

defines a loading aperture such that the catheter may be loaded or adjusted into the inner cavity through the loading aperture” has been deleted from claims 1 and 11, so as to remove the duplication of this claim limitation.

Claims 2 and 12 are believed to now be in condition for allowance.

II. Rejection under 35 U.S.C. § 112, second paragraph

Claims 3-4 and 13-14 were rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite in claiming the subject matter of the invention. Specifically, the Examiner stated that the use of the phrase “no longer than a human hand” in claims 3-4 and 13-14 are relative terms, due to human hands not being a standard unit of measurement, thereby rendering the claims indefinite. The Examiner further stated that based on the use of such claim language, one of skill in the art would be unable to determine what size would be too large to be outside of the scope of the claimed invention.

Applicant has cancelled claims 3-4 and 13-14. Consequently, this rejection is now moot. Applicant respectfully requests that the rejections of claims 3-4 and 13-14 under 35 U.S.C. § 112, second paragraph be withdrawn.

III. Rejection under 35 U.S.C. § 102

Claims 1-5, 7 and 10-16 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 3,683,928 to Kuntz (hereinafter “the Kuntz Patent”). The Examiner states that the Kuntz Patent discloses a catheter applicator which includes a sidewall with a distal end piece, a proximal end piece, a loading aperture, an inner cavity, and a dispensing aperture.

For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). Further, inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present in the prior art. *In re Robertson*, 169 F.3d 743, 49 USPQ.2d 1949 (Fed. Cir. 1999).

The Kuntz Patent describes a urethral catheter applicator having a catheter storage cartridge 12 (see FIGS 1-4), a first container 14 disposed over and forward of cartridge 12, a coiled spring 16 that is in front of container 14, a second container 18 disposed over and in front of spring 16 and first container 14, and a nose portion 20 connected to the front of second container 18, thus forming yet another container. The second container 18 is described as being “slightly larger than container 14 and is nested over and spaced from container 14 by spring 16” (column 3, lines 10-12). The catheter is also described as having a means for lubricating (*via* lubricant well 74) and unidirectionally advancing (*via* the reciprocating spring action of spring 16; column 4, lines 16-36) a catheter through and from the device 10 while the device is held and manipulated with one hand. All of the embodiments shown and described in the Kuntz patent (see Figure 2 reproduced below), both in the specification and in the claims, suggest an applicator that is operated in a mechanical manner (for instance, by a coiled spring 16 or resilient strips 86), and that has more than one separate and distinct chambers. In fact there are at least three distinct chambers in the device claimed by Kuntz.

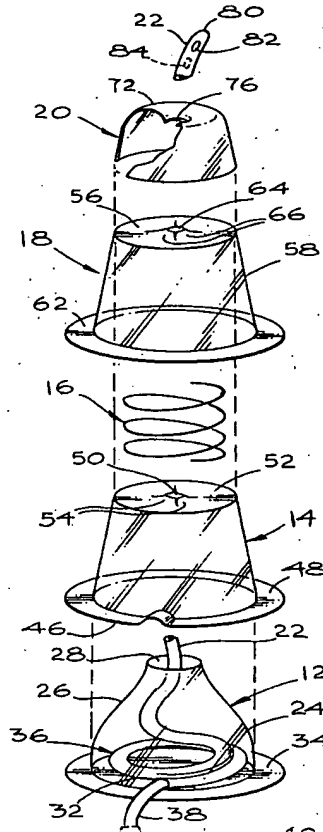


FIG. 2 of the Kuntz Patent, reproduced.

Applicant's present invention is directed to an epidural catheter dispenser system capable of use with one hand, and methods for the use of such an apparatus. As described in the specification and the claims as amended, the catheter dispenser system of the present invention comprises at least one sidewall 2 (referring to FIGS 1A-1D) having a proximal end and a distal end. The proximal end is connected to a proximal end piece 3, which simultaneously defines a loading aperture 7 and the bottom border of the single inner cavity 5, while the distal end is connected to distal end piece 4 which has an aperture 6 and defines the upper border of the single inner cavity 5 (see below).

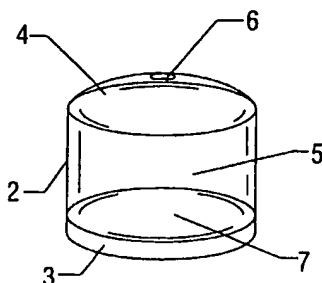


Figure 1D of the present invention, reproduced

The Kuntz Patent does not disclose or suggest an epidural catheter dispenser system having a single inner cavity. In fact, the Kuntz Patent proposes only a catheter applicator device having at least three separately defined cavities, each having their own distinct function. Applicant's independent claims 1 and 10 (and newly added claim 51) describe a catheter dispenser system having a single inner cavity. Because this element of the Applicant's claimed invention is not shown or described in the Kuntz Patent, this reference does not anticipate claims 1-5, 7 and 10-16 under 35 U.S.C. § 102(b).

Applicant respectfully requests that the rejections of claims 1-5, 7 and 10-16 under 35 U.S.C. § 102 be withdrawn.

IV. Rejection under 35 U.S.C. § 103

Claims 6, 8-9, and 17-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over the Kuntz Patent. According to the Examiner, Kuntz meets all of the claim limitations of these claims, save for the positioning of the dispenser toward the user's thumb. The Examiner further states that it would have been obvious to turn the dispenser in any orientation, so as to enhance the comfort of the device during use and/or to enhance usability of the device. Additionally, the Examiner states that it would have been obvious to change the

shape of the sidewalls of the device to be a cylinder or polyhedron, and that it would have been obvious to load the catheter mechanically or by an automated process, thereby enhancing the sterility of the device.

According to MPEP § 706.02(j), for a claim to be obvious, there must be a) a suggestion or motivation to combine reference teachings, b) a reasonable expectation of success, and c) the references must teach all of the claim limitations, *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The cited reference fails to teach all of the claim limitations.

The Kuntz patent is discussed extensively above. As mentioned, the device described and claimed by Kuntz comprises a first container 14 disposed over and forward of cartridge 12, a coiled spring 16 that is in front of container 14, a second container 18 disposed over and in front of spring 16 and first container 14, and a nose portion 20 connected to the front of second container 18, thus forming yet another container.

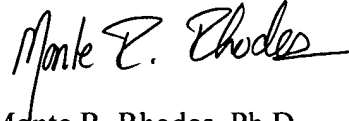
The pending claims describe an epidural catheter dispenser system having a single inner cavity. The instant application clearly establishes the use of a single chambered, hand-held catheter application device to administer an epidural catheter in a sterile, socioeconomic fashion. Because the cited reference fails to teach this claim limitation of a single chambered device, the Applicant's claimed invention is not obvious in view of the Kuntz Patent. In fact, in view of the device taught by Kuntz, one would be motivated not to have only one chamber due to sterility issues, and would rather be motivated to have several chambers in place to serve a variety of sterility and lubricating functions. Accordingly, Applicant requests that the rejections of claims 6, 8-9 and 17-18 under 35 U.S.C. § 103 be withdrawn.

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In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All amendments are made in a good faith effort to advance the prosecution on the merits. Applicant respectfully submits that no amendments have been made to the pending claims for the purpose of overcoming any prior art rejections that would restrict the literal scope of the claims or equivalents thereof. Applicant reserves the right to subsequently take up prosecution of the claims originally filed in this application in continuation, continuation-in-part, and/or divisional applications.

The Examiner is encouraged to call the undersigned should any further action be required for allowance.

Respectfully submitted,



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